

### **REMARKS**

After entry of this amendment, claims 1, 5, 8-11, 13, 15, 18-19, 29, 32, 47, and 49 are pending. Claims 21, 25, 34, 41, and 45 have been cancelled without prejudice or disclaimer as being directed to non-elected subject matter. Applicants preserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications. The claims have been amended without prejudice or disclaimer to address the various points made in the Official Action. Support is found *inter alia* in the original claims. Further support for the amendment made to claims 1, 18, 19, 29, 47 and 49 is found in the specification at page 20, lines 17-20. Claims 1, 29, 47, and 49 find further support at page 13, lines 21-24. No new matter has been added.

### **Claim Objections**

The Examiner objects to claims 1, 18, and 29 for informalities. Claims have been amended as suggested by the Examiner. In view of the amendment, it is believed that the objections are rendered moot. Reconsideration and withdrawal of the objections is respectfully requested.

### **Double Patenting**

Claims 1, 5, 8-11, 13, 15, 18, 19, 29, 32, 47, and 49 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 2, 10-12, 15, 16, 19, and 22-27 of co-pending Application No. 11/251,208. As stated in the Amendment and Reply Under 37 CFR § 1.111 dated May 7, 2007, Applicants propose to overcome this rejection by filing a terminal disclaimer upon the indication of otherwise allowable subject matter.

### **Claim Rejections – 35 U.S.C. § 112**

Claims 1, 5, 8-11, 13, 15, 18, 19, 29, 32, 47, and 49 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking an enabling disclosure and failing to comply with the written description requirement. Applicants respectfully disagree. However, to expedite prosecution, claims have been amended without prejudice or disclaimer to recite the polypeptide encoded by the ORSRP coding nucleic acid and the environmental stresses with more specificity. Applicants respectfully submit that claims as amended overcome the rejections.

### ***Enablement Rejection***

The Examiner rejects the claims for lack of enablement, alleging that the specification is only enabled for an ORSRP coding nucleic acid sequence encoding the protein of SEQ ID NO: 4, but not the variants or homologs of SEQ ID NO: 4. The Examiner argues that the specification, and/or the state of the art, does not provide guidance on which region(s), or which amino acid residues, of the encoded protein, SEQ ID NO: 4, can be altered without abrogating abiotic stress tolerance property. Applicants respectfully disagree and traverse the rejection.

As disclosed at pages 50-51 and 57, the specification provides detailed guidance including working examples on how to clone a glutaredoxin gene (*i.e.* an ORSRP gene, Examples 1 and 2) and how to test tolerance to various environmental stresses that is conferred by the expression of such a glutaredoxin gene in transgenic plants (Example 1). Furthermore, the specification discloses conserved regions of the glutaredoxin subfamily of which SEQ ID NO: 4 is a member (page 58, lines 12-16 and Figures 2-4), which provides guidance as to potential substitutions or modification. In view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the claimed subject matter without undue experimentation. On these facts, an analysis under *In re Wands* supports enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

This analysis is in consistent with the Board's decision in *Ex parte Kubin*, 83 USPQ2d 1410 (B.P.A.I. 2007)(hereinafter "*Kubin*"), where the Board held that a claim encompassing 80% amino acid sequence identity to the disclosed sequence was fully enabled. *Kubin*, at 1416. As the Board noted in *Kubin*, even though practicing the full scope of the claims might have required extensive experimentation, the experimental techniques were well known in the art, so the experimentation would have been routine and thus, not undue. *Id.*, at 1416.

As in *Kubin*, the experimentation required to practice the present claims (making and screening mutant sequences having at least 95% identity to SEQ ID NO: 4) is routine in nature and clearly not "undue." Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner further alleges that the specification is not enabling for any biotic or abiotic stress property associated with high temperature, metal, chemical, pathogenic and/or

oxidative stresses. Applicants respectfully disagree. However, to expedite prosecution, claims have been amended without prejudice or disclaimer to recite the environmental stresses with more specificity. While certain stresses are recited, improvements in other stresses tolerance may be inherent. Reconsideration and withdrawal of this rejection is respectfully requested.

***Written Description Rejection***

The Examiner further rejects the claims for lack of enablement, alleging that the specification describes only the sequence of SEQ ID NO: 3 that encodes the polypeptide of SEQ ID NO: 4. The Examiner further argues that the specification does not describe the structures of the claimed genus that correlate to the function of abiotic stress tolerant property. Applicants respectfully traverse and submit that the claims as amended relates to a subject matter clearly described.

“A description of a genus of cDNAs may be achieved by means of ... a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” *The Regents of The University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The glutaredoxin family is characterized by the standard glutaredoxin domain with the consensus sequence as provided in the specification at page 58, lines 8-9. By sequence alignment between various glutaredoxins from different species, the specification further identifies and discloses two conserved domains of the glutaredoxin subfamily of which SEQ ID NO: 4 is a member (“subfamily 1,” page 58, lines 12-16 and Figures 2-4). It is further noted that these two conserved domains distinguish the subfamily 1 from other subfamilies of glutaredoxins.

The disclosure of the conserved domains and the polypeptide sequence of SEQ ID NO: 4, and the pre-existing knowledge in the art regarding the genetic code and its redundancies would have put one skilled artisan in possession of the genus of nucleic acids that encode SEQ ID NO: 4. Additionally, with the aid of various computer programs available at the time of filing, one skilled in the art could have readily envisioned all of the nucleic acids that encode a polypeptide with at least 95% sequence identity with SEQ ID NO: 4. Accordingly, one of ordinary skill in the art would conclude that Applicants were in possession of the genus of nucleic acid molecules as recited in the claims at the time the application was filed.

In light of the amendment, Applicants respectfully submit that the claims satisfy the written description requirement. Reconsideration and withdrawal of the rejection is respectfully requested.

**Claim Rejection – 35 USC § 103**

Claims 1, 5, 8-11, 13, 15, 18, 19, 29, 32, 47, and 49 stand rejected under 35 U.S.C. § 103(a) as being obvious over Gan in view of Valvekens and Grant.

To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

As discussed in the Amendment and Reply Under 37 CFR § 1.111 dated May 7, 2007, Gan discloses a yeast glutaredoxin gene that is 100% identical to the sequence of SEQ ID NO: 3. **Gan does not teach or suggest a transgenic plant with such a nucleic acid sequence.** Valvekens generally teaches a method for plant cell transformation and regeneration of transgenic plants. Grant teaches that the yeast glutaredoxin GRX 2, which corresponds to SEQ ID NO: 4, may play a role in “response to various stress conditions” or “protecting against oxidative stress” in yeast cells. **Grant however does not teach or suggest that a transgenic plant expressing yeast GRX2 would exhibit improved tolerance to stresses.** Accordingly, the references, when combined, do not support a *prima facie* conclusion of obviousness as alleged by the Examiner.

Nevertheless, the Examiner alleges that the stress-protective function of glutaredoxin in yeast cells as taught in Grant would motivate a skilled artisan to express the same nucleic acid in any eukaryotic cells including plant cells to produce a transgenic plant cell which is tolerant to stress. The Examiner argues that the routine practice in using a yeast expression system to isolate and establish the function of unknown plant genes provides further motivation to one skilled in the art to overexpress any useful yeast protein, including GRX2, in a plant to obtain abiotic stress tolerant plant with reasonable expectation of success. Additionally, the Examiner alleges that the routine use of yeast expression system for screening for plant gene function implies that it would have been obvious for one skilled artisan to overexpress a well

characterized (yeast) protein such as GRX2 in a plant to obtain abiotic tolerance with reasonable expectation of success. Applicants respectfully disagree.

Contrary to the Examiner's allegation, a showing of stress tolerance in yeast with one gene would not necessary create an expectation that the same results would be achieved in plants using the same gene. Although both are eukaryotic organisms, various differences exist between yeast and plant. For example, the yeast such as *Saccharomyces cerevisiae* has a genome size of 13 Mbp that contains 5,570 protein-encoding genes, while the relatively simple model plant organism *Arabidopsis thaliana* has a genome size of 125 Mbp containing 25,498 protein-encoding genes (see Brock, Biology of Microorganisms, 11th edition, page 491, Table 15.3). This is approximately 1,000% difference in genome size and about 500% difference in protein-encoding gene numbers. Furthermore, both organisms are completely different at the cellular level: yeast is a unicellular fungus while plant is a multicellular organism. Moreover, yeast has a completely different heritage concerning the phylogenetic tree as compared to a plant. Together with other differences not enumerated here, a yeast gene identified in yeast does not necessary indicate that the same gene would function the same way when transformed into a different organism such as a plant. Similarly, the routine use of yeast expression system to express a plant gene and to identify plant gene function does not imply that overexpressing a yeast gene in a plant would function the same way as it does in the yeast. Such a general motivation does not direct with specificity towards the invention claimed.

Thus, the references, when combined, suggest, but do not clearly establish, that the yeast glutaredoxin GRX2 (*i.e.* SEQ ID NO: 4) may play a role in protecting against oxidative stress in yeast cells. It was totally unpredictable that a transgenic plant expressing yeast GRX2 would exhibit improved tolerance to stresses. Absent the hindsight afforded by a reading of Applicants' disclosure, it could not have been predicted that transforming a plant cell or plant with yeast glutaredoxin GRX2 coding sequence or related sequences would confer improved stress tolerance of the types claimed. It would have been only speculative whether a plant cell or plant transformed with yeast glutaredoxin GRX2 would exhibit increased tolerance to environmental stresses in view of the differences between these two organisms as discussed above and further in view of the fact that yeast is not an art-recognized model for plant study. There is no basis to

believe that the stress tolerance mechanisms in yeast and in plant are identical or even similar. Accordingly, the subject matter as claimed would not have been obvious.

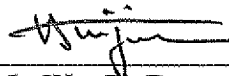
Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

### CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a three-month extension of time to and including May 14, 2008, to respond to the Office Action mailed November 14, 2007, and a Request for Continued Examination with the required fee authorization. No further fees are believed due. If any additional fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13311-00012-US from which the undersigned is authorized to draw.

Respectfully submitted,

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